510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k110894

B. Purpose for Submission:

This submission is for a modification of the Contour USB System (K091820). This modification includes a new reagent strip and addition of wireless transmission capabilities with compatible Medtronic MiniMed devices (Medtronic MiniMed Paradigm Insulin pumps or Medtronic MiniMed Paradigm REAL-Time Revel Insulin Pumps or Medtronic MiniMed Paradigm® REAL-TIME Insulin Pumps or Guardian REAL-TIME Monitor).

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose dehydrogenase (FAD)

E. Applicant:

Bayer HealthCare LLC, Diabetes Care

F. Proprietary and Established Names:

CONTOUR® NEXT LINK Wireless Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LFR – Glucose dehydrogenase, glucose	Class II	21 CFR § 862.1345	75-Chemistry
NBW – system, test, blood glucose, over the counter	Class II	21 CFR § 862.1345	75-Chemistry
JJX – Quality Control material	Class I, reserved	21 CFR § 862.16	75-Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The CONTOUR® NEXT LINK Wireless Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single-patient use only and should not be shared. The CONTOUR® NEXT LINK Wireless Blood Glucose Monitoring System is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. The system consists of a Contour NEXT LINK wireless blood glucose meter, CONTOUR® NEXT test strips and CONTOUR® NEXT control solutions.

   CONTOUR® NEXT test strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL.

   The CONTOUR® NEXT control solutions are aqueous glucose solutions intended for use in self-testing by people with diabetes as a quality control check.

   The CONTOUR® NEXT LINK Wireless Blood Glucose Monitoring System is intended to be used to transmit glucose values to Medtronic MiniMed Paradigm Insulin pumps or Medtronic MiniMed Paradigm REAL-Time Revel Insulin Pumps or Medtronic MiniMed Paradigm® REAL-TIME Insulin Pumps or Guardian REAL-TIME Monitor and facilitate transfer of information to Medtronic MiniMed Carelink Therapy Management Software through use of radio frequency communication.

   The CONTOUR® NEXT LINK Wireless Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

3. Special conditions for use statement(s):

   For over-the-counter use and for prescription use

   For single-patient use only

   For use with fresh capillary whole blood samples drawn from the fingertip and

palm only

Not for neonatal use, not for screening or diagnosis of diabetes mellitus.

May be used to transmit glucose values to compatible Medtronic MiniMed devices and facilitate transfer of information to Medtronic MiniMed Carelink® Therapy Management Software through use of radio frequency communication.

Not for use on critically ill patients (e.g. those with severe hypotension or shock, hyperglycemic-hyperosmolar state, hypoxia, severe dehydration, diabetic ketoacidosis).

4. Special instrument requirements:

   Contour NEXT LINK Wireless Blood Glucose Meter

I. Device Description:

The Contour® NEXT LINK Wireless Blood Glucose Monitoring System which consists of a small handheld electronic device is the same in look and feel as the Contour® USB predicate system (K091820). The system also contains dry reagent strips and liquid controls to be used for the measurement of glucose in capillary whole blood by persons with diabetes. The system is automatically coded as the predicate device. Blood glucose results are displayed on the meter window and stored in the meter's memory. The system also contains radio frequency (RF) functions for the sending of BGM results to compatible Medtronic Minimed insulin pumps. The RF function can also serve as a pass through for data being transmitted from Medtronic Minimed insulin pumps to Medtronic's Minimed PC based data management software.

The CONTOUR® NEXT LINK Wireless Blood Glucose Monitoring System consists of the following components:

- CONTOUR® NEXT LINK blood glucose meter
- CONTOUR® NEXT blood glucose test strips
- CONTOUR® NEXT control solution – Level 1
- CONTOUR® NEXT control solution – Level 2

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bayer's CONTOUR® USB System

2. Predicate K number(s):

k091820

3. Comparison with predicate:

Item	**Candidate device** **Bayer's Contour NEXT LINK Wireless**	**Predicate device** **Bayer's Contour USB** (k091820)
Intended Use/Indications for Use	Same	For the quantitative measurement of glucose in whole blood.
	Same	Over-the-counter (OTC)
	Home settings. For single patient use only.	Home settings and in healthcare facilities.
	Fingertip and palm sampling only	Fingertip, palm and forearm sampling.
	May be used to transmit glucose values to compatible Medtronic MiniMed devices and facilitate transfer of information to Medtronic MiniMed Carelink® Therapy Management Software through use of radio frequency communication.	No RF capability
Detection method	Same	Amperometry
Calibration Coding	Same	No coding by user
Test range	Same	20-600 mg/dL
Sample volume	Same	0.6 µL
Reagent strips*	CONTOUR NEXT test strip	CONTOUR test strip
Controls**	CONTOUR NEXT control solutions	CONTOUR control solutions
Double Dip Function***	Yes	No
Moisture Damage Detection****	Yes	No
Algorithm*****	Multi-pulse	Single point
Memory	1000 test results	2000 test results

* Test Strips
The Contour NEXT test strips utilize the same enzyme as the predicate Contour test strips (FAD-GDH). The same fundamental technology is also used for obtaining a blood glucose result. They differ in the fact that a different mediator is utilized - MLB mediator (3-(2', 5'-Disulfophenylimino-3H-phenothiazine) bis sodium salt) while the predicate utilizes Potassium Ferricyanide. The MLB mediator reduces background current and allows for a lower applied voltage.
The Contour NEXT test strips have a different electrode pattern that can be used only on the Contour NEXT LINK device and are not compatible with the predicate device Contour USB meter (K091820).

** Control Solutions
The Contour NEXT control solutions are identical in chemical composition to the Contour control solutions (predicate k091820). They differ in the concentration of the buffer BIS-TRIS (BT). The BT concentration in the Contour NEXT control solution is lower. The lower concentration allows the Contour NEXT sample identification algorithm to detect control and provide sufficient signal differentiation between blood and control solution.

***Double Dip Function
A software feature that allows the user to add additional blood after initially applying an insufficient sample (less than 0.6 uL) is present.

**** Moisture Damage Detection
A software feature that detects sensors that are exposed to humidity for long periods of time is present. If this condition is detected, an error is flagged and the glucose result is not calculated.

*****Algorithm
The Contour NEXT LINK device, when Contour NEXT test strip is utilized, employs an algorithm where the current is measured at several points in time (multi-pulse algorithm). The predicate device (K091820) uses an algorithm where the current is measured at a single point in time. The multi-pulse algorithm allows for additional mathematical compensations regarding hematocrit and temperature effects.

K. Standard/Guidance Document Referenced (if applicable):

ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

ISO 14971: Medical devices – Application of risk management of medical devices

L. Test Principle:

The CONTOUR® NEXT LINK wireless blood glucose test is based on measurement of electrical current caused by the reaction of glucose with the reagents on the electrode of the strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and potassium ferricyanide. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed. No calculation is required.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within-run precision was evaluated using venous blood samples at five glucose concentrations across the measuring range. Three lots of test strips were tested each on 10 meters with 10 replicates per meter (N=100/Lot). Results are summarized below:

Within-run precision for glucose:

Strip Lot	Mean (mg/dL)	SD	% CV
1	41.3	0.7	1.6%
	78.9	1.0	1.3%
	120.6	1.9	1.6%
	205.6	4.4	2.1%
	334.4	4.4	1.3%

Strip Lot	Mean (mg/dL)	SD	% CV
2	40.9	0.6	1.6%
	79.6	0.8	1.0%
	120.9	1.2	1.0%
	204.5	4.1	2.0%
	330.0	5.8	1.7%

Strip Lot	Mean (mg/dL)	SD	% CV
3	40.7	0.6	1.6%
	79.4	1.2	1.5%
	121.9	1.3	1.1%
	205.9	3.8	1.8%
	331.6	4.5	1.4%

Between-day precision was evaluated using three levels of control solutions (Level 1, 2 and 3). One measurement was taken per meter on 10 meters over the course of 10 days using each of the three lots of strips tested. Results are summarized below:

Between-day precision for glucose:

Strip Lot	Mean (mg/dL)	SD	CV%
1	45.2	0.7	1.6
	130.9	2.0	1.5
	387.8	6.7	1.7
2	44.2	0.6	1.4
	130.4	2.0	1.5
	377.5	5.9	1.6
3	42.9	0.6	1.4
	128.0	2.0	1.6
	374.2	5.5	1.5

b. *Linearity/assay reportable range:*

Linearity for Contour Next test strip was established in this submission using the Contour Next Link wireless meter. A fresh venous blood pool was divided into eight aliquots and glycolyzed at room temperature or supplemented with a glucose stock solution to produce whole blood samples with plasma glucose concentrations across the intended measuring range. All samples were tested on 8 Contour Next Link meters using 3 lots of test strips to generate 24 test results and these results were plotted against the YSI reference values in the liner regression analysis. The result of the regression analysis is summarized in the below table:

Strip Lot /Meter	Slope	95% CI slope	Intercept	95% CI intercept	R^2
Lot 1	1.00	0.998 to1.007	-1.5	-1.614 to -1.291	0.9993
Lot 2	1.02	1.015 to 1.027	-1.6	-1.863 to -1.417	0.9988
Lot 3	0.94	0.938 to 0.946	3.5	3.336 to 3.644	0.9993
3 lot/8 meters	0.99	0.983 to 0.993	0.2	-0.030 to 0.352	0.998

Based on these results, the sponsor claims a measuring range of 20-600 mg/dL for the Contour Next Link wireless blood glucose monitoring system.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability:

Traceable to NIST SRM 91, dry D-glucose.

Value assignment:

The value assignment of the Contour NEXT control solutions were determined by an in-house procedure. The control solutions were prepared by gravimetric addition of glucose to achieve target values of 120 mg/dL for level 1 and 350 mg/dL for level 2. During release, each lot of Contour NEXT Test Strips is tested with Contour NEXT Controls (n = 36 per control level), and a range of ±11% around the mean is assigned as the control range for each control level.

Stability:

Real time stability was performed to assess the shelf-life and open-vial stability of the control solutions and test strips. Stability studies protocol and acceptance criteria were provided and found to be adequate. Unopened control solutions have an 18 month shelf life and are stable for 6 months after first use when stored at 48-86 ^{o}F (9^{o}C -30^{o}C). The stability data also supports an 18-month unopened bottle shelf life and an open-vial use-life for the

Contour NEXT test strips under storage temperature range of 41-86 °F (5ºC - 30ºC). This information is provided in the labeling of the test strips and control materials.

d. Detection limit:

See linearity study above.

e. Analytical specificity:

Interference

The interference studies were carried out using three lots of Contour NEXT test strips. A pool of fresh whole blood at 80 mg/dL and 300 mg/dL plasma glucose was measured using the YSI method. The interferents were tested in a dose-response method at different levels meeting and exceeding the maximum concentration of the substance expected to be encountered in clinical practice. A total of 24 replicates per sample were collected for the six most common interfering substances (acetaminophen, ascorbic acid, bilirubin, uric acid, maltose, galactose) on eight Contour Next meters with each of the three lots of Contour NEXT test strips. The interference studies for the common drugs and anticoagulants were done by collecting 10 replicates from each of the three Contour NEXT test lots on five Contour Next Link Meters. In addition to testing compounds that were known to interfere with electrochemical glucose monitoring systems, testing was also conducted with a variety of common exogenous and endogenous compounds as also listed in the below table.

Effect of Interferences at the Upper End of Normal or Therapeutic Range

Compound	Test Levels	Normal or Therapeutic / Reference Range	%Deviation at Upper Limit of Range	Limiting Concentration (<10% Interference)
Acetaminophen (mg/dL)	11, 22, 35	1.0-2.0	≤ ± 1%	35
Ascorbic Acid (mg/dL)	1, 8, 12, 15, 22	0.4-2.0	≤ ± 1%	10
Bilirubin (mg/dL)	1, 16, 32, 45, 58	0.3-1.2	≤ ± 1%	54
Caffeine (mg/dL)	2, 3, 7	0.5-2.0	≤ ± 1%	7
Cholesterol (mg/dL)	170, 457, 652, 1149, 1171	150-300	≤ ± 1%	1168
Creatinine HCl (mg/dL)	8, 17, 34	0.8-1.7	≤ ± 1%	34
Dopamine HCl (mg/dL)	4.0, 7.3, 14.6	0.04	≤ ± 1%	4
Ephedrine (mg/dL)	1, 5.6, 11	0.005-0.01	≤ ± 1%	11
Galactose (mg/dL)	112, 224, 336	5.0	≤ ± 1%	336
Sodium Gentisate (mg/dL)	28, 56, 112	0.2-0.7	≤ ± 1%	112
Glutathione (mg/dL)	17, 35, 140, 280	0.11	≤ ± 1%	17
Hemoglobin (g/dL)	2, 2.6, 5.3, 11.6	0.1-0.2	≤ ± 1%	2
Ibuprofen (Na salt) (mg/dL)	11, 28, 56	1.7-7.8	≤ ± 1%	56
Icodextrin (g/dL)	0.6, 1.1, 2	0.5	≤ ± 1%	2
L-Dopa (mg/dL)	0.3, 1.3, 5.0	0.02-0.3	≤ ± 1%	5
Maltose (mg/dL)	112, 224, 336	120	≤ ± 1%	336

Methyl Dopa (mg/dL)	0.6, 1.7, 3.0	0.1-0.75	≤ ± 1%	3
Na Salicylate (mg/dL)	28, 56, 112	11.5-34.7	≤ ± 1%	112
Tetracycline (mg/dL)	1.1, 2.2, 4.0	0.2-0.5	≤ ± 1%	4
Tolazamide (mg/dL)	28, 56, 112	3.0	≤ ± 1%	112
Tolbutamide (mg/dL)[21]	28, 56, 112	5.4-10.8	≤ ± 1%	112
Triglycerides (mg/dL)	88, 915, 2538, 4063, 5667	190	≤ ± 1%	4709
Uric Acid (mg/dL)	4, 20, 44, 70	2.5-8.0	≤ ± 1%	59
Xylose (mg/dL)	6, 56, 112, 224	57	51%	6

The sponsor defined "significant interference" is +/-10% bias. Based on the test results, the sponsor has provided the following statements in the labeling:

- Xylose: Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.

- Lipemic Specimen: Cholesterol concentrations >1,168 mg/dL or triglyceride concentrations >4,709 mg/dL may produce inaccurate results.

- Reducing substances occurring in the blood naturally (uric acid, bilirubin) or from therapeutic treatments (ascorbic acid, acetaminophen) will not significantly affect results.

- Interference might occur when the values of the limiting concentrations of these compounds are greater than those listed below:
  Bilirubin >54 mg/dL
  Uric Acid >59 mg/dL
  Ascorbic Acid >10 mg/dL
  Acetaminophen >35 mg/dL
  Maltose no interference
  Galactose no interference

- CONTOUR NEXT test strip results are not significantly affected by hematocrit levels in the range of 15% to 65%.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with reference method (*YSL*):

System accuracy was evaluated according to the ISO 15197 document using

100 participants from a diabetic clinic. A trained HCP collected fingerstick sample from each participant. Each sample was tested in singlet using three different glucose reagent strip lots, 10 vials per lot to yield 300 total results. Six meters were used—two with each reagent strip lot. Fingerstick samples were analyzed on an YSI 2300 STAT PLUS analyzer to provide reference values. The analyses were performed at 23 ±0.5 ºC.

In most cases, samples were tested fresh from the finger without any modification. Altered samples (10% of total) were created by either glycolyzing a specimen to lower the glucose concentration or supplementing a specimen with a concentrated glucose solution to increase the glucose level. The distribution of the sample glucose concentrations is specified in the table below.

Sample description:

Glucose Concentration (mg/dL)	Number of samples		
	Total	Natural Capillary Blood	Modified Capillary Blood
< 50	5	1	4
50 - 80	15	12	3
81 - 120	20	20	0
121 - 200	30	30	0
201 - 300	15	15	0
301 - 400	10	9	1
> 400	5	3	2
Total	100	90	10

ISO 15197 Acceptance Criteria:

95% of individual glucose results shall fall within ±15mg/dL of reference method at glucose concentrations < 75mg/dL and within ± 20% at glucose concentrations ≥ 75mg/dL.

Result Summary:

Glucose < 75 mg/dL (17 samples)

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Overall	48 of 51 (94.1%)	51 of 51 (100.0%)	51 of 51 (100.0%)
Lot 1	15 of 17 (88.2%)	17 of 17 (100.0%)	17 of 17 (100.0%)
Lot 2	17 of 17 (100.0%)	17 of 17 (100.0%)	17 of 17 (100.0%)
Lot 3	16 of 17	17 of 17 (100.0%)	17 of 17 (100.0%)

	(94.1%)		

Glucose ≥ 75 mg/dL (83 Samples)

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
Overall	212 of 249 (85.1%)	247 of 249 (99.2%)	249 of 249 (100.0%)	249 of 249 (100.0%)
Lot 1	73 of 83 (88.0%)	81 of 83 (97.6%)	83 of 83 (100.0%)	83 of 83 (100.0%)
Lot 2	69 of 83 (83.1%)	83 of 83 (100%)	83 of 83 (100.0%)	83 of 83 (100.0%)
Lot 3	70 of 83 (84.3%)	83 of 83 (100%)	83 of 83 (100.0%)	83 of 83 (100.0%)

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

User performance study was performed to compare the lay user self-test results and the YSI method. Study was performed in one clinical site in US with 110 subjects with type 1 or type 2 diabetes, age 19-86 (mean age of 53), and 47% male. All subjects performed fingerstick tests (i.e. capillary) and palm tests; the results were compared to the YSI laboratory reference results from fingerstick blood. Three test strip lots were tested in the study, with each subject randomized to one lot.

The range of glucose values for the finger stick samples was 43-558 mg/dL measured by YSI. Linear regressions analysis results are summarized below:

Regressions between lay user's fingerstick results and the YSI method:

Tester	Linear regressions	N
Lay user-finger stick	Y=0.99X+0.43	110
Lay user-palm	Y=1.00X-3.33	109 (One subject did not complete palm testing due to low blood sugar)

Accuracy by ISO 15197 Criteria:

Fingerstick Glucose < 75 mg/dL (8 samples)

Number of test results	Within ± 5 mg	Within ± 10 mg	Within ± 15 mg
8	8 of 8 (100%)	8 of 8 (100%)	8 of 8 (100%)

Fingerstick Glucose ≥ 75 mg/dL (102 Samples)

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
102	82 of 102 (80.4%)	101 of 102 (99.0%)	101 of 102 (99.0%)	102 of 102 (100.0%)

Palm Glucose < 75 mg/dL (7 samples)

Number of test results	Within ± 5 mg	Within ± 10 mg	Within ± 15 mg
7	6 of 7 (85.7%)	7 of 7 (100%)	7 of 7 (100%)

Palm Glucose ≥ 75 mg/dL (102 Samples)

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
102	61 of 102 (58.8%)	90 of 102 (88.2%)	98 of 102 (96.1%)	99 of 102 (97.1%)

N=109, one subject could not complete palm testing due to low blood sugar.

100% of the test results generated by lay user-finger stick, 97.3% of the test results generated by lay user-palm, fall within the acceptance limits of ±15mg/dL (<75 mg/dL) or ±20% (>75mg/dL).

4. Clinical cut-off**:**

Not applicable.

5. Expected values/Reference range:

   Expected blood glucose results were cited from the literature[1] and presented in the labeling as follows:

   Non diabetic plasma glucose concentrations are normally maintained within a relatively narrow 70-110 mg/dL in the fasting state. You should consult with your healthcare provider for expected glucose values specific to your needs.

   [1] Longo DL, et al.: Harrison's Principles of Internal Medicine-18th edition, 2011:3003.

N. Instrument Name:

CONTOUR Next Link Wireless blood glucose meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 0.6 uL.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ___X_____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes ___X_____ or No _____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X_____ or No _____

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   The glucose test is intended to be used with capillary whole blood from the finger and palm. The whole blood sample is applied directly to the test strip by capillary

action.

5. Calibration:

   There is no calibration required for the CONTOUR® -Next Link blood glucose meter by the user. The meter is automatically coded.

6. Quality Control:

   Glucose control solutions at 2 different concentrations can be run with this device and Control level 2 is provided with the kit. The meter automatically distinguishes control solution from blood and marks control solution tests with a check mark and excludes them from average calculations. Recommendations on when to test the control materials are provided in the labeling. An acceptable range for each control level is printed on the test strip bottle label or on the bottom of the test strip box. The user is cautioned not to use the meter if the control result falls outside these ranges.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. Flesch-Kincaid readability assessment was conducted and the results showed that the labeling (User Guide, test strip package insert and control solution package insert) were written at or lower than the 8^{th} grade level.

2. Customer service is available 24 hours/day, 365 days a year. Toll free phone number is 1-800-348-8100 for Bayer Diabetes Care customer support.

3. Temperature and humidity operating conditions were evaluated for temperatures ranging from 41^{o}F-113^{o}F (5^{o}C to 45^{o}C) and relative humidity from 10% to 93% including extreme combinations of temperature and humidity, e.g. lowest humidity with lowest and highest temperature and highest humidity with lowest and highest temperature. Protocol and acceptance criteria were provided and found to be acceptable. The results supported the Sponsor's claimed operating temperature from 41^{o}F-113^{o}F and relative humidity range from 10% to 93%.

4. EMC testing was performed by an accredited EMC Testing Laboratory. A test certificate was issued to Bayer on March 30, 2011.

5. The device is intended for single-patient use only. Clorox® Germicidal Wipes containing 0.55% sodium hypochlorite with EPA registration # 67619-12 was validated demonstrating complete inactivation of live virus using materials from the meter and lancing device. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 260 cleaning and disinfection cycles designed to simulate cleaning and disinfection 1x per week for 5 years. Labeling was reviewed for

adequate instructions for the validated cleaning and disinfection procedures.

6. Altitude Study

   To ensure that high altitudes will not affect the system performance, a study was conducted inside a glove box purged with ultra pure nitrogen to simulate high altitude at 22,552 feet (6874 meters).

   Two lots of reagent test strips were tested on five Contour®Next Link wireless meters in duplicate (total n=10) with 15, 41, and 65% hematocrit whole blood supplemented to achieve target plasma glucose levels of 40, 90, and 450 mg/dL. Mean assay results obtained inside the glove box were compared to the plasma YSI glucose values, and to the lab-elevation values. The difference for glucose values <75mg/dL and the percent difference for glucose values ≥75 mg/dL was calculated. The mean bias across all hematocrit levels for glucose values <75mg/dL and ≥75 mg/dL are acceptable.

   The results support a system claim of up to 6874 meters (22,552 feet).

7. Hematocrit study:

   The hematocrit sensitivity of the Contour Next Link system was evaluated. Three lots of reagent test strips were tested on five Contour® Next Link wireless meters in triplicate (total n = 15) with 15, 20, 30, 42, 55 and 65% hematocrit whole blood at 5 glucose concentrations of 40, 90, 127, 329 and 450 mg/dL. Sample bias was calculated relative to the YSI reference method. The results support the sponsor's claim that the system is accurate in hematocrit range of 15-65%.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.